



S/N 10/675,818

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	KNUDSON ET AL.	Examiner:	UNKNOWN
Serial No.:	10/675,818	Group Art Unit:	UNKNOWN
Filed:	SEPTEMBER 29, 2003	Docket No.:	14283.1USI2
Title:	ENTERIC RHYTHM MANAGEMENT		

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 29, 2003.

By:

Name:

Debra A Bailey
Debra A Bailey

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted within three months of the filing date of the above-identified application, which is not an application under 37 C.F.R. § 1.53(d). Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. § 1.98(a)(2) and § 1.98(d), copies have been provided only for those non-U.S. Patent items listed on the enclosed Form 1449 that have not previously been cited by or submitted to the U.S. Patent and Trademark Office in parent application, U.S. Serial No. 10/358,093 filed on February 3, 2003. As the filing date of this application is after June 30, 2003, copies of the U.S. Patents listed are not supplied.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a

reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

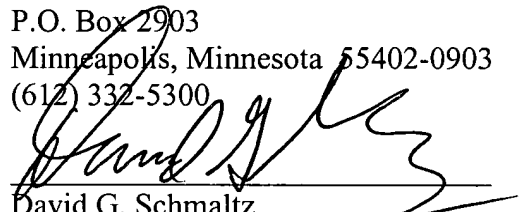
Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: 12/29/03



David G. Schmaltz
Reg. No. 39,828
DGS:PLSdb

23552

PATENT TRADEMARK OFFICE

FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 14283.1USI2	Application Number: 10/675,818
	Applicant: KNUDSON ET AL.	
	Filing Date: 09/29/2003	Group Art Unit: UNKNOWN

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,188,104	February 23, 1993	Wernicke et al.			
	5,215,086	June 1, 1993	Terry, Jr. et al.			
	5,231,988	August 3, 1993	Wernicke et al.			
	5,263,480	November 23, 1993	Wernicke et al.			
	5,269,303	December 14, 1993	Wernicke et al.			
	5,292,344	March 8, 1994	Douglas			
	5,299,569	April 5, 1994	Wernicke et al.			
	5,330,515	July 19, 1994	Rutecki et al.			
	5,335,657	August 9, 1994	Terry et al.			
	5,540,730	July 30, 1996	Terry, Jr. et al.			
	5,571,150	November 5, 1996	Wernicke et al.			
	5,690,691	November 25, 1997	Chen et al.			
	5,707,400	January 13, 1998	Terry, Jr. et al.			
	5,716,385	February 10, 1998	Mittal et al.			
	5,836,994	November 17, 1998	Bourgeois			
	5,861,014	January 19, 1999	Familoni			
	5,919,216	July 6, 1999	Houben et al.			
	5,995,872	November 30, 1999	Bourgeois			
	6,083,249	July 4, 2000	Familoni			
	6,091,992	July 18, 2000	Bourgeois et al.			
	6,093,167	July 25, 2000	Houben et al.			
	6,097,984	August 1, 2000	Douglas			
	6,098,629	August 8, 2000	Johnson et al			
	6,104,955	August 15, 2000	Bourgeois			
	6,135,978	October 24, 2000	Houben et al.			
	6,216,039 B1	April 10, 2001	Bourgeois			
	6,238,423 B1	May 29, 2001	Bardy			
	6,243,607 B1	June 5, 2001	Mintchev et al.			

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FORM 1449*

INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

Docket Number:

14283.1USI2

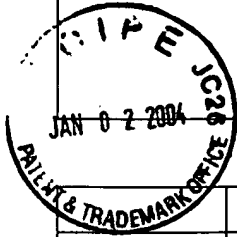
Application Number:

10/675,818

Applicant: KNUDSON ET AL.

Filing Date: 09/29/2003

Group Art Unit: UNKNOWN



	6,261,280 B1	July 17, 2001	Houben et al.			
	6,405,732 B1	June 18, 2002	Edwards et al.			
	6,449,511 B1	September 10, 2002	Mintchev et al.			
	6,473,644 B1	October 29, 2002	Terry, Jr. et al.			
	6,571,127 B1	May 27, 2003	Ben-Haim et al.			
	6,610,713 B2	August 26, 2003	Tracey			
	2002/0055779 A1	May 9, 2002	Andrews			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

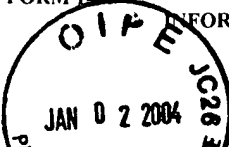
		Aggarwal A, et al., "Predominant Symptoms in Irritable Bowel Syndrome Correlate with Specific Autonomic Nervous system Abnormalities", <u>Gastroenterol.</u> , (1994);106:945-950
		Amaris et al., "Microprocessor controlled movement of solid colonic content using sequential neural electrical stimulation", <u>Gut</u> , 50: pp 475 - 479 (2002)
		Batterham, et al., "Inhibition of Food Intake in Obese Subjects by Peptide YY3-36", <u>New England J. Med.</u> , pp. 941 - 948 (September 4, 2003)
	X	Beglinger et al., "Postprandial Control of Gallbladder Contraction and Exocrine Pancreatic Secretion in Man", <u>Euro. J. of Clinical Investigation</u> , pp. 827 - 834 (1992)
	X	Bell, et al., "The Interplay between Hydrogen Ions, Bicarbonate Ions and Osmolality in the Anterior Duodenum Modulating Gastric Function in the Conscious Calf", <u>J. Physiol.</u> , pp. 331 - 341 (1981)
	X	Benini, "Gastric Emptying and Dyspeptic Symptoms in Patients with Gastroesophageal Reflux", <u>Amer. J. of Gastroenterology</u> , pp. 1351 - 1354 (1996)
	X	Benini, et al., "Omeprazole Causes Delay in Gastric Emptying of Digestible Meals", <u>Digestive Diseases and Sciences</u> , pp. 469 - 474 (1996)
	X	Berthoud et al., "Characteristics of Gastric and Pancreatic Responses to Vagal Stimulation with Varied Frequencies: Evidence for Different Fiber Calibers?", <u>J. Auto. Nervous Sys.</u> , pp. 77 - 84 (1987)
	X	Bourde, et al., "Vagal Stimulation: II. Its Effect on Pancreatic Secretion in Conscious Dogs", <u>Annals of Surgery</u> , pp. 357 - 364 (1970)

- Missing items marked with "X"

EXAMINER

DATE CONSIDERED


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FORM 1449*  INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 14283.1US12	Application Number: 10/675,818
	Applicant: KNUDSON ET AL.	
	Filing Date: 09/29/2003	Group Art Unit: UNKNOWN

		Cann PA, et al. "Irritable Bowel Syndrome: Relationship of Disorders in the Transit of a Single Solid Meal to Symptoms Patterns", <u>Gut</u> , (1983);24:405-411 ✓
	*	Chey et al., "Neural Hormonal Regulation of Exocrine Pancreatic Secretion", <u>Pancreatology</u> , pp. 320 – 335 (2001)
	*	Chey, "Regulation of Pancreatic Exocrine Secretion", <u>Int'l J. of Pancreatology</u> , pp. 7 – 20 (1991)
		Cuomo R, et al., "Functional Dyspepsia Symptoms, Gastric Emptying and Satiety Provocation Test: Analysis of Relationships", <u>Scand J Gastroenterol</u> , (2001) 36:1030-1036 ✓
		Dapoigny et al., "Vagal influence on colonic motor activity in conscious nonhuman primates", <u>Am. J. Physiol.</u> , 262: G231 – G236 (1992) ✓
	*	DeVault KR, et al., "Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease", <u>Am J Gastroenterol</u> , (1999);94:1434-1442
		Drossman, "Rome II: A Multinational Consensus Document on Gastrointestinal Disorders – The Functional Gastrointestinal Disorders and the Rome II Process", <u>Gut</u> , Vol. 45 (Suppl II):II1-II5 (1999) ✓
	*	Estevão-Costa et al., "Delayed Gastric Emptying and Gastroesophageal Reflux: A Pathophysiologic Relationship", <u>J. of Pediatric Gastroenterology and Nutrition</u> , pp. 471 – 474 (2001)
		Evans PR, et al., "Gastroparesis and Small Bowel Dysmotility in Irritable Bowel Syndrome", <u>Dig Dis Sci</u> (1997);42:2087-2093 ✓
		Evans PR, et al., "Jejunal Sensorimotor Dysfunction in Irritable Bowel Syndrome: Clinical and Psychosocial Features", <u>Gastroenterol</u> , (1996);110:393-404 ✓
		Gershon, "The Second Brain", Harper Collins Publishers, Inc, New York, NY p. 19 (1998) ✓
	*	Grossi, et al., "Swallows, Oesophageal and Gastric Motility in Normal Subjects and in Patients with Gastro-Oesophageal Reflux Disease: a 24-H pH-Manometric Study", <u>Neurogastroenterology and Motility</u> , pp. 115 – 121 (1998)
		Guyton AC, et al., "Propulsion and Mixing of Food in the Alimentary Tract", <u>Textbook of Medical Physiology</u> , 10 th ed. Philadelphia: W. B. Saunders and Company, 200:728-737 ✓
		Guyton AC, et al., "Secretory Functions of the Alimentary Tract", <u>Textbook of Medical Physiology</u> , 10 th ed. Philadelphia: W. B. Saunders and Company, 200:738-753 ✓
		Hausken, et al., "Low Vagal Tone and Antral Dysmotility in Patients with Functional Dyspepsia", <u>Psychosomatic Medicine</u> , 55: 12 – 22 (1993) ✓
		Heitkemper, et al., "Evidence for Automatic Nervous System Imbalance in Women with Irritable Bowel Syndrome", <u>Digestive Diseases and Sciences</u> , Vol. 43, No. 9, pp. 2093 – 2098 (1998) ✓
		Hjelland, et al., "Vagal tone and meal-induced abdominal symptoms in healthy subjects", <u>Digestion</u> , 65: 172 – 176 (2002)
		Holst <i>et al</i> "Nervous control of pancreatic endocrine secretion in pigs" <u>Acta Physiol Scand</u> , (1981), 111:1-7 ✓
		Hornbuckle K, et al. "The Diagnosis and Work-Up of the Patient with Gastroparesis", <u>J Clin Gastroenterol</u> , (2000);30:117-124 ✓
	*	Hunt, "The Relationship Between The Control Of pH And Healing And Symptom Relief In Gastro-Oesophageal Reflux Disease", <u>Ailment Pharmacol Ther.</u> , 9 (Suppl. 1) pp. 3 – 7 (1995)

– Missing items marked with *

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FORM 1449*  INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 14283.1USI2	Application Number: 10/675,818
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	*	Kaminski et al., "The Effect of Electrical Vagal Stimulation on Canine Pancreatic Exocrine Function", Surgery, pp. 545 – 552 (1975)	
		Kellow JE, et al., "Dysmotility of the Small Intestine in Irritable Bowel Syndrome", <u>Gut</u> , (1988);29:1236-1243	✓
		Kellow JE, et al., "Rome II: A Multinational Consensus Document on Gastrointestinal Disorders – Principles of Applied Neurogastroenterology: Physiology/Motility-Sensation", <u>Gut</u> , (1999);45(Suppl II):II17-II24	✓
		Korner et al., "To Eat or Not to Eat – How the Gut Talks to the Brain", <u>New England J. Med.</u> , pp. 926 – 928 (September 4, 2003)	✓
		Lagergren J, et al., "Symptomatic Gastroesophageal Reflux as a Risk Factor for Esophageal Adenocarcinoma", <u>New Engl J Med</u> , (1999);340:825-831	✓
		Lin et al., "Hardware – software co-design of portable functional gastrointestinal stimulator system", <u>J. of Medical Eng. & Tech.</u> , Vol. 27, No. 4 pp. 164 – 177 (2003)	✓
	*	Long, M.S. editor, Chapter 3, "The Stomach", Gastrointestinal System, 2 nd Ed., Mosby Publisher, London (2002)	
	*	Long, M.S. editor, Chapter 4, "The Liver and Biliary Tract", Gastrointestinal System, 2 nd Ed., Mosby Publisher, London (2002)	
	*	Mabayo, et al., "Inhibition of Food Passage by Omeprazole in the Chicken", <u>European J. of Pharmacology</u> , pp. 161 – 165 (1995)	
		Merio R, et al., "Slow Gastric Emptying in Type I Diabetes: Relation to Autonomic and Peripheral Neuropathy, Blood Glucose, and Glycemic Control", <u>Diabetes Care</u> , (1997);20:419-423	✓
		Mintchev, et al., "Electrogastrographic impact of multi-site functional gastric electrical stimulation", <u>J. of Medical Eng. & Tech.</u> , Vol. 23, No. 1 pp. 5 – 9 (1999)	✓
		Mittal RK, et al., "Mechanism of Disease: The Esophagogastric Junction", <u>New Engl J Med</u> , (1997);336:924-932	✓
		Novartis product description, Zelnorm [®] , July 2002 (T2002-19)	✓
	*	Owyang, "Negative Feedback Control of Exocrine Pancreatic Secretion: Role of Cholecystokinin and Cholinergic Pathway", Symposium: Physiology of Cholecystokinin, American Institute of Nutrition, pp. 1321S – 1326S (1994)	
		Paterson CA, et al., "Determinants of Occurrence and Volume of Transpyloric Flow During Gastric Emptying of Liquids in Dogs: Importance of Vagal Input", <u>Dig Dis Sci</u> , (2000);45:1509-1516	✓
		Petrofsky, et al., "Impact of Recruitment Order on Electrode Design for Neural Prosthetics of Skeletal Muscle", <u>Am. J. of Physical Medicine</u> , Vol. 60, No.5, pp. 243 – 253 (1981)	✓
		Poelmans J, et al., "Prospective Study on the Incidence of Chronic Ear Complaints Related to Gastroesophageal Reflux and on the Outcome of Antireflux Therapy", <u>Ann Otol Rhinol Laryngol</u> , (2002);111:933-938	✓
		Rashev et al., "Microprocessor-Controlled Colonic Peristalsis", <u>Digestive Diseases and Sciences</u> , Vol. 47, No. 5, pp. 1034 – 1048 (2002)	✓
		Rashev, et al., "Three-dimensional static parametric modeling of phasic colonic contractions for the purpose of microprocessor-controlled functional stimulation", <u>J. of Medical Eng. & Tech.</u> , Vol. 25, No. 3 pp. 85 – 96 (2001)	✓
	*	Rasmussen, et al., "A Double-Blind Placebo-Controlled Study on the Effects of Omeprazole on Gut Hormone Secretion and Gastric Emptying Rate", <u>Scand. J. Gastroenterol</u> , pp. 900 – 905 (1997)	

– Missing items marked with "*"

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<input checked="" type="checkbox"/>	Rösch et al., "Frequency-Dependent Secretion of Pancreatic Amylase, Lipase, Trypsin, and Chymotrypsin During Vagal Stimulation in Rats", <u>Pancreas</u> , pp. 499 – 506 (1990)
<input checked="" type="checkbox"/>	Sarnelli G, et al., "Symptoms Associated with Impaired Gastric Emptying of Solids and Liquids in Functional Dyspepsia", <u>Am J Gastroenterol</u> , (2003) 98:783-788
<input checked="" type="checkbox"/>	Scheffer RC, et al., "Elicitation of Transient Lower Oesophageal Sphincter Relaxations in Response to Gastric Distension", <u>Neurogastroenterol Motil</u> , (2002);14:647-655
<input checked="" type="checkbox"/>	Schapiro, et al., "Neurohypophyseal Regulation of the Exocrine Pancreas", <u>Amer. J. of Gastroenterology</u> , pp. 587 – 591 (1979)
<input checked="" type="checkbox"/>	Schmidt T, et al., "Ambulatory 24-Hour Jejunal Motility in Diarrhea-Predominant Irritable Bowel Syndrome", <u>J Gastroenterol</u> , (1996);31:581-589
<input checked="" type="checkbox"/>	Schwartz MP, et al., "Chemospecific Alterations in Duodenal Perception and Motor Response in Functional Dyspepsia", <u>Am J Gastroenterol</u> , (2001);96:2596-2602
<input checked="" type="checkbox"/>	Schwartz MP, et al., "Human Duodenal Motor Activity in Response to Acid and Different Nutrients", <u>Dig Dis Sci</u> , (2001);46:1472-1481
<input checked="" type="checkbox"/>	Simren M, et al., "Abnormal Propagation Pattern of Duodenal Pressure Waves in the Irritable Bowel Syndrome (IBS)", <u>Dig Dis Sci</u> , (2000);45:2151-2161
<input checked="" type="checkbox"/>	Solomonow, et al., "Control of Muscle Contractile Force through Indirect High-Frequency Stimulation", <u>Am. J. of Physical Medicine</u> , Vol. 62, No. 2, pp. 71 – 82 (1983)
<input checked="" type="checkbox"/>	Sontag SJ, et al., "Asthmatics with Gastroesophageal Reflux: Long Term Results of a Randomized Trial of Medical and Surgical Antireflux Therapies", <u>Am J Gastroenterol</u> , (2003);98:987-999
<input checked="" type="checkbox"/>	Stanghellini V, et al., "Risk Indicators of Delayed Gastric Emptying of Solids in Patients with Functional Dyspepsia", <u>Gastroenterol</u> , (1996) 110:1036-1042
<input checked="" type="checkbox"/>	Tack J, et al., "Role of Impaired Gastric Accommodation to a Meal in Functional Dyspepsia", <u>Gastroenterol</u> , (1998) 115:1346-1352
<input checked="" type="checkbox"/>	Tack J, et al., "Symptom Pattern and Gastric Emptying Rate Assessed by the Octanoic Acid Breath Test in Functional Dyspepsia" [abstract]. <u>Gastroenterol</u> , (1998) 114:A301
<input checked="" type="checkbox"/>	Talley et al., "Rome II: A Multinational Consensus Document on Gastrointestinal Disorders – Functional Gastrointestinal Disorders" <u>Gut</u> , Vol. 45 (Suppl II), pp. I37-II42 (1999)
<input checked="" type="checkbox"/>	Thompson WG, et al., "Rome II: A Multinational Consensus Document on Gastrointestinal Disorders – Functional Bowel Disorders and Functional Abdominal Pain", <u>Gut</u> , (1999) ;45(Suppl II):II43-II47
<input checked="" type="checkbox"/>	Tiscornia et al., "Neural Control of the Exocrine Pancreas: An Analysis of the Cholinergic, Adrenergic, and Peptidergic Pathways and Their Positive and Negative Components I: Neural Mechanisms", <u>Mount Sinai J. of Medicine</u> , pp. 366 – 383 (1987)
<input checked="" type="checkbox"/>	Tougas, "The Autonomic Nervous System in Functional Bowel Disorders", <u>Gut</u> , Vol. 47 (Suppl IV), pp. iv78-iv80 (2000)
<input checked="" type="checkbox"/>	Undeland KA, et al., "Wide Gastric Antrum and Low Vagal Tone in Patients with Diabetes Mellitus Type 1 Compared to Patients with Functional Dyspepsia and Healthy Individuals", <u>Dig Dis Sci</u> , (1996) 41:9-16
<input checked="" type="checkbox"/>	Van Den Honert, et al., "Generation of Unidirectionally Propagated Action Potentials in a Peripheral Nerve by Brief Stimuli", <u>Science</u> , Vol. 206, pp. 1311 – 1312

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	X	Van Wijk HJ, et al., "Gastric Emptying and Dyspeptic Symptoms in the Irritable Bowel Syndrome", <u>Scand J Gastroenterol</u> , (1992);27:99-102
		Vassallo MJ, et al., "Colonic Tone and Motility in Patients with Irritable Bowel Syndrome", <u>Mayo Clin Proc</u> , (1992);67:725-731
		Wilmer A, et al., "Ambulatory Gastrojejunal Manometry in Severe Motility-like Dyspepsia: Lack of Correlation between Dysmotility, Symptoms and Gastric Emptying", <u>Gut</u> , (1998) 42:235-242

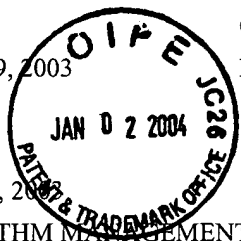
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Confirmation No.: UNKNOWN
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Title: ENTERIC RHYTHM MANAGEMENT



CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 29, 2003.

By: Debra A Bailey

Name: Debra A Bailey

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

23552

PATENT TRADEMARK OFFICE

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Information Disclosure Statement, Form 1449, 50 Reference(s)
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Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT & GOULD P.C.
P.O. Box 2903, Minneapolis, MN 55402-0903
612.332.5300

By: David G. Schmaltz

Name: David G. Schmaltz

Reg. No.: 39,828

DSchmaltz:PLSdb